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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/670,399      | 09/27/2000  | Masao Washizu        | 001268              | 7255             |

23850 7590 02/14/2003

ARMSTRONG, WESTERMAN & HATTORI, LLP  
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EXAMINER

BROWN, JENNINE M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1755

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/670,399 | <b>Applicant(s)</b><br>WASHIZU ET AL. |  |
|                              | <b>Examiner</b><br>Jennine M. Brown  | <b>Art Unit</b><br>1755               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Objections***

Examiner has entered Applicants amendment, which obviates Examiners objection, therefore the objection has been withdrawn.

### ***Specification***

Examiner appreciates and has entered Applicants amendment, which more clearly defines Applicants invention and clears the record.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Regnier, et al. (US 5958202).

Regarding claims 1-3 and 8, Regnier, et al. teach a method of forming a complex substance to separate out a specific molecule from a mixture by applying a dielectrophoretic field (col. 1, l. 29-33) then detection to give qualitative measurement

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of the separated specific molecule (col. 1, l. 33-50) where the application deals with separation of proteins, nucleic acids and cells (col. 1, l. 29-33).

Regarding claims 4-6 and 7-10, Regnier, et al. teach a method of forming a tethered complex (e.g. coated bead or channel) which is bound to the specific molecule (e.g. substrate or antibody) but not bound to the (e.g. enzyme or antigen) complex substance which then binds to the tethered specific molecule (coated bead or channel with substrate or antibody) complex substance, separated out by dielectrophoresis and detected to get a qualitative measurement of the specific molecule where the application is specifically related to enzyme labeled antigen (col. 9, l. 26 – col. 10, l. 10).

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Becker, et al. (US 6294063).

Becker, et al. teach an equivalence between movement of sample ("packets") by electrophoretic forces and dielectrophoretic forces (Figure 2; col. 3, l. 42-46; col. 7, l. 63 – col. 8, l. 5; col. 8, l. 31-35). Becker, et al. also teach a method of forming a complex substance to separate out a specific molecule from a mixture by applying a dielectrophoretic field then detection to give qualitative measurement of the separated specific molecule where the application deals with separation of proteins, nucleic acids and cells (Figures 1, 9B, 12; col. 2, l. 59-63; col. 3, l. 17-23; col. 4, l. 6-10; col. 5, l. 66 – col. 7, l. 4; col. 14, l. 46 – col. 15, l. 7; col. 28, l. 28 – col. 30, l. 44).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regnier, et al. (US 5958202) in view of Becker, et al. (US 6294063).

Regnier, et al. teach some mixing of solutions to be detected may have to be done at high potential for a method of forming a complex substance to separate out a specific molecule from a mixture by applying a dielectrophoretic field then detection to give qualitative measurement of the separated specific molecule previously formed by a tethered complex (e.g. coated bead or channel) bound to the specific molecule (e.g. substrate or antibody) but not bound to the (e.g. enzyme or antigen) complex substance which then binds to the tethered specific molecule (coated bead or channel with substrate or antibody) complex substance. Becker, et al. teach an equivalence

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between movement of sample ("packets") by electrophoretic forces and dielectrophoretic forces as well as a microchip format and method of detecting position and controlling movement by varied means. It would have been obvious to one of ordinary skill in the art to use the apparatus of Regnier, et al. for both electrophoretic or dielectrophoretic processes because the electrodes can be set by the controller for any type of voltage or current whether AC or DC as described in Becker, et al. (col. 8, l. 31-35) and would be set to apply either a homogeneous or inhomogeneous field to move the sample. The system used in electrophoresis is essentially the same as that used for dielectrophoresis, the only difference is whether or not a homogeneous field or inhomogeneous field is sent to the electrodes by the controller.

Regnier, et al. in view of Becker, et al. do not specifically teach the voltage range of 500 KV/m. It would have been obvious to one of ordinary skill in the art to determine, through routine experimentation the optimum voltage range to pulse around the sample to mix it properly so that binding occurs and detection of the complex will occur. It is known in the art to vary any one of the result-effective parameters to optimize separation. Clearly voltage is a result-effective parameter.

### ***Response to Arguments***

1. Rejection under 35 U.S.C. Section 102(e):

Regarding claims 1-10, Regnier, et al. teach an electrophoretic apparatus which would be able to be used for dielectrophoresis since the apparatus inherently possesses the features necessary for dielectrophoresis (e.g. electrodes and controllers in contact

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with the substrate) where the electric field may be AC or DC and/or a combination of both which would create an inhomogeneous electrical field causing migration or electrorotation of the sample according to the formula presented by Applicants.

Applicants arguments are based on a difference in electrophoretic and dielectrophoretic theory rather than the application of said apparatus to the separation of a sample and the apparatus that is used to separate the sample. Although Applicants recite the use of an inhomogeneous field, it does not distinguish the method of separation over that of electrophoresis since the method is essentially the same whether AC or DC or a mixture of AC and DC is used for the electrodes. The rejection is maintained.

2. Rejection under 35 U.S.C. Section 103(a):

Applicant's arguments with respect to claims 14-23 have been considered but are moot in view of the new grounds of rejection.

***Relevant Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5993631 teaches different voltages used to move sample throughout a channel using electrodes for a dielectrophoretic force for a sample comprised of an antigen and first antibody connected to a microparticle and in a second embodiment also having a second amplifier antibody and dielectric label attached to the antigen antibody microparticle complex to be detected by the dielectrophoretic system.



***Conclusion***

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennine M. Brown whose telephone number is (703) 305-0435. The examiner can normally be reached on M-F 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on (703) 308-3823. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 879-9310 for regular communications and (703) 872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

jmb  
February 6, 2003

  
**Mark L. Bell**  
**Supervisory Patent Examiner**  
**Technology Center 1700**